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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,101	06/16/2000	Patrick de Baetselier	4432US	2709

7590 06/17/2003

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/596,101	DE BAETSELIER ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see Attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-3, 11, 13 and 16-17*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER

Advisory Action Attachment

1. Applicant's response filed July 19, 2002 is acknowledged. Applicant's submission of Exhibit A is acknowledged, however, the source of Exhibit A has not been disclosed by the Applicant.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

3. The rejection of claims 1-3 and 13 under 35 U.S.C. 102(b) as anticipated by Bilej et al *(European Cytokine Network, March-April 1994)* is maintained for the reasons set forth on pages 2-3 of the previous Office Action.

The rejection was on the grounds that Bilej et al teach a coelomic fluid from the *Eisenia foetida* earthworm that exerts a strong trypanolytic activity. Bilej et al teach that the coelomic fluid of the earthworm contains strong proteolytic, hemolytic, bacteriolytic and cytolytic factors and may be an ancestral form of TNF-α. It would be inherent that the CCF-1 protein as taught by Bilej et al would comprise at least 9 contiguous amino acids of SEQ ID No: 1 or comprise the amino acid sequence of SEQ ID NO: 3 or a functional fragment thereof.

Since the Office does not have the facilities for examining and comparing applicant's polypeptide with the polypeptide of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that they have attached Exhibit A indicating that the claimed peptide (rCCF-1) does not possess significant cytolytic (i.e. hemolytic) activity while the Bilej et al reference indicates that the "Coelomic fluid of the earthworm *Eisenia foetida*

(Annelida) contains strong proteolyic, hemolytic, bacteriolytic and cytolytic factors." Applicant urges that the claimed peptide does not possess the same functional characteristics as the coelomic fluid disclosed in Bilej et al.

Applicant's arguments filed July 19, 2002 have been fully considered but they are not persuasive. The claims are drawn to a peptide comprising at least 9 contiguous amino acids of SEQ ID NO.1. Claim 3 recites "the peptide of claim 1 exhibits trypanolytic activity" and claim 13 recites "the peptide of claim 2 exhibits trypanolytic activity". It is the Examiner's position that the Applicant is arguing limitations that are not in the claims. There is no requirement or limitation in the claims that requires that the claimed peptide not possesses proteolyic, hemolytic, bacteriolytic or cytolytic as functional characteristics. Bilej et al, *(European Cytokine Network, March-April* (1994)) of record teach a coelomic fluid from the *Eisenia foetida* earthworm that exerts a strong trypanolytic activity which is a requirement of the claimed invention. Bilej et al also teach that the coelomic fluid of the earthworm contains strong cytolytic factors. Although Applicant's have submitted Exhibit A to disclose that the CCF-1 protein is not hemolytic, this functional characteristic is not a requirement of the claimed peptide. It should be noted that the instant specification teaches coelomic fluid (CF) of *E. foetida* exerts a trypanolytic activity on *T. brucei* parasites (page 14) and teaches that coelomic fluid is trypanolytic for *Trypanosoma cruzi* (page 15). It should also be noted that the instant specification teaches that the rCCF-1 has both trypanolytic activity and cytolytic activity (page 20). Organisms of the genus *Trypanosoma* are unicellular eukaryotes. Trypanolytic activity is the lysing of trypanosomes. Therefore, coelomic

fluid would exert cytolytic activity since *Trypanosoma brucei and Trypanosoma cruzi* are unicellular organisms and the specification teaches that coelomic fluid lyses organisms (lyses the cell) of the genus *Trypanosoma* (pages 14 and 15). The claimed peptide is anticipated by the Bilej et al, since Bilej et al teach a coelomic fluid from the *Eisenia foetida* earthworm that exerts a strong trypanolytic activity which is a requirement of the claimed invention. Therefore, the peptide of the prior art meets the limitations of the claimed peptide. Further the exhibit is heresay inasmuch it is not presented in declarative form pursuant to 37 CFR 1.132. Additionally, the data clearly indicates and Applicants admit that the claimed peptide does in fact possess hemolytic activity. Additionally, since the peptide is not purified or isolated the semi-pure active fraction reads on the claims. There is no evidence of record that the semi-pure fraction of the art is not a peptide comprising SEQ ID NO.3 or a fragment thereof or a peptide comprising at least 9 contiguous amino acids of SEQ ID NO.1.

4. The rejection of claims 11 and 16-17 under 35 U.S.C. 102(b) as anticipated by Bilej et al *(Immunology Letters, 45, 1995)* is maintained for the reasons set forth on pages 3-4 of the previous Office Action.

The rejection was on the grounds that Bilej et al teach a concentrated coelomic fluid composition for intra-foot pad immunization of Balb/c mice (see page 124). The composition of Bilej et al is the same as the claimed invention. It would be inherent that the concentrated coelomic fluid sample would contain a peptide comprising at least 9 contiguous amino acids of SEQ ID NO: 1 or a peptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment/epitope of either thereof.

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition with the pharmaceutical composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical

composition of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that they have attached Exhibit A indicating that the claimed peptide (rCCF-1) does not possess significant cytolytic (i.e. hemolytic) activity while the Bilej et al reference indicates that the "Coelomic fluid of the earthworm *Eisenia foetida* (Annelida) contains strong proteolyic, hemolytic, bacteriolytic and cytolytic factors." Applicant urges that the claimed peptide does not possess the same functional characteristics as the coelomic fluid disclosed in Bilej et al.

Applicant's arguments filed July 19, 2002 have been fully considered but they are not persuasive. The claims are drawn to a composition comprising at least a peptide selected from the group of peptides consisting of a peptide comprising at least 9 contiguous amino acids of SEQ ID NO.1, a peptide comprising the amino acid sequence of SEQ ID NO.3, a fragment of either thereof and an epitope of either thereof. It is the Examiner's position that the Applicant is arguing limitations that are not in the claims. There is no requirement or limitation in the claims that requires that the claimed peptide possesses proteolyic, hemolytic, bacteriolytic or cytolytic as functional characteristics. Bilej et al, (*Immunology Letters* (1995)) of record teach a concentrated coelomic fluid composition for intra-foot pad immunization of Balb/c mice (page 124). Bilej et al also teach that the coelomic fluid of the earthworm possess cytolytic activities. Although Applicant's have submitted Exhibit A to disclose that the CCF-1 protein is not hemolytic, this functional characteristic is not a requirement of the claimed peptide. It should be noted that the instant specification teaches coelomic fluid (CF) of *E. foetida*

exerts a trypanolytic activity on *T. brucei* parasites (page 14) and teaches that coelomic fluid is trypanolytic for *Trypanosoma cruzi* (page 15). It should also be noted that the instant specification teaches that the rCCF-1 has both trypanolytic activity and cytolytic activity (page 20). Organisms of the genus *Trypanosoma* are unicellular eukaryotes. Trypanolytic activity is the lysing of trypanosomes. Therefore, coelomic fluid would exert cytolytic activity since *Trypanosoma brucei and Trypanosoma cruzi* are unicellular organism and the specification teaches that coelomic fluid lyses organisms (lyses the cell) of the genus *Trypanosoma* (pages 14 and 15). The claimed pharmaceutical is anticipated by the Bilej et al, since Bilej et al teach a concentrated coelomic fluid composition for intra-foot pad immunization of Balb/c mice. Therefore, the pharmaceutical composition of the prior art meets the limitations of the claimed pharmaceutical composition.

5. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
June 11, 2003